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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/554,295	08/15/2006	Christopher M. Counter	1579-1047	4470

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EXAMINER	
FRONDA, CHRISTIAN L	
ART UNIT	PAPER NUMBER
1652	
MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/554,295	COUNTER ET AL.	
	Examiner	Art Unit	
	CHRISTIAN L. FRONDA	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 March 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *8-23 and 25-45* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *10* is/are allowed.

6)☒ Claim(s) *8,9,11-23 and 25-45* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *26 October 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/1/2010*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 8-23 and 25-45 (new claims 42-45) are pending and under consideration in the instant Office Action.

Claim Rejections - 35 U.S.C. § 101

2. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

3. Claim 9 is rejected under 35 USC 101 because the claimed invention is directed to non-statutory subject matter.

Claim 9, as written, does not sufficiently distinguish over nucleic acids as they exist naturally because the claims do not particularly point out any non-naturally occurring differences between the claimed products and the naturally occurring products. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. *See Diamond v. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (1980). The claims should be amended to indicate the hand of the inventor, e.g., by insertion of "Isolated" or "Purified". See MPEP 2105.

Claim Rejections - 35 U.S.C. § 112, 1st Paragraph

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 8, 11-23, 25-45 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The arguments filed 03/01/2010 have been considered but are not persuasive for reasons of record as supplemented below.

While the references of Nakamura et al. and Bryan et al. teach reverse transcriptases and the specification refers to different moieties regarding the telomere binding polypeptide component of the claimed chimeric molecule, the structural limitations and properties cannot be read into the claims. According to MPEP §2111, claims must be given their broadest reasonable interpretation consistent with the specification and that such interpretation of the claims must also be consistent with the interpretation that those skilled in the art would reach. The claims of the instant invention must be read in light of the specification to thereby interpret limitations explicitly recited in the claims. Thus, limitations of the specification cannot be read into the claims to narrow the scope of the claims by implicitly adding disclosed limitations which are not recited in the claims. The instant specification only describes an isolated polynucleotide comprising SEQ ID NO: 1 encoding the hPot1-hTERT fusion protein which elongates telomeres in human cell lines.

The previous rejection of record is reproduced below.

The claims are genus claims encompassing a genus of nucleic acids encoding chimeric molecules comprising polypeptides having telomerase catalytic activity fused to telomere binding polypeptides including Potl, TRF1, TRF2, PinX1, Rapl, Tin2, Tankyrase, TANK2 and Ku70/80, where the polypeptides having telomerase catalytic activity comprise a catalytic subunit of mammalian telomerase reverse transcriptases. The scope of the genus includes many members with widely differing nucleotide sequences, amino acid sequences, and/or structures, where the genus is highly variable because a significant number of structural and biological differences between genus members exists. The specification, however, does not describe and define any structural features, amino acid sequences, and/or biological functions that are commonly possessed by members of the genus, other than SEQ ID NO: 1.

MPEP § 2163 states that a representative number of species means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus. In this case, the specification fails to disclose additional nucleic acids encoding chimeric molecules as claimed other than the isolated polynucleotide of SEQ ID NO: 1. As such the disclosure of the isolated polynucleotide of SEQ ID NO: 1 is insufficient to be representative of the attributes and features common to all the members of the claimed genus.

Vas-Cath, Inc. v. Mahurkar, 19USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116). One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class, where the specification provided only the bovine sequence.

In view of the above considerations, one of skill in the art would not recognize that applicants were in possession of the genus of nucleic acids encoding chimeric molecules comprising polypeptides having telomerase catalytic activity fused to telomere binding polypeptides including Potl, TRF1, TRF2, PinX1, Rapl, Tin2, Tankyrase, TANK2 and Ku70/80, where the polypeptides having telomerase catalytic activity comprise a catalytic subunit of mammalian telomerase reverse transcriptases.

6. Claims 8, 11-23, 25-45 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated polynucleotide comprising SEQ ID NO: 1, a vector comprising said isolated polynucleotide comprising SEQ ID NO: 1, composition comprising said isolated polynucleotide comprising SEQ ID NO: 1, and an isolated cell comprising said isolated polynucleotide comprising SEQ ID NO: 1; **does not** reasonably provide enablement for any nucleic acid encoding any chimeric molecule comprising any polypeptide

having telomerase catalytic activity fused to any telomere binding polypeptide including Potl, TRF1, TRF2, PinX1, Rapl, Tin2, Tankyrase, TANK2 and Ku70/80, where the polypeptide having telomerase catalytic activity comprises any catalytic subunit of any mammalian telomerase reverse transcriptase. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. The arguments filed 03/01/2010 have been considered but are not persuasive for reasons of record as supplemented below.

While the references of Nakamura et al. and Bryan et al. teach reverse transcriptases and the specification refers to different moieties regarding the telomere binding polypeptide component of the claimed chimeric molecule, the structural limitations and properties cannot be read into the claims. According to MPEP §2111, claims must be given their broadest reasonable interpretation consistent with the specification and that such interpretation of the claims must also be consistent with the interpretation that those skilled in the art would reach. The claims of the instant invention must be read in light of the specification to thereby interpret limitations explicitly recited in the claims. Thus, limitations of the specification cannot be read into the claims to narrow the scope of the claims by implicitly adding disclosed limitations which are not recited in the claims. The instant specification only provides enablement for an isolated polynucleotide comprising SEQ ID NO: 1 encoding the hPot1-hTERT fusion protein which elongates telomeres in human cell lines.

The previous rejection of record is reproduced below.

According to MPEP 2164.01(a), factors considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue" include, but are not limited to: (A) The breadth of the claims; (B) The nature of the invention; (C) The state of the prior art; (D) The level of one of ordinary skill; (E) The level of predictability in the art; (F) The amount of direction provided by the inventor; (G) The existence of working examples; and (H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure. MPEP§ 2164.04 states that while the analysis and conclusion of a lack of enablement are based on the factors discussed in MPEP § 2164.01(a) and the evidence as a whole, it is not

necessary to discuss each factor in the written enablement rejection. The language should focus on those factors, reasons, and evidence that lead the examiner to conclude that the specification fails to teach how to make and use the claimed invention without undue experimentation, or that the scope of any enablement provided to one skilled in the art is not commensurate with the scope of protection sought by the claims. Accordingly, the factors most relevant to the instant rejection are addressed in detail below.

The nature and breadth of the amended claims encompass any nucleic acid encoding any chimeric molecule comprising any polypeptide having telomerase catalytic activity fused to any telomere binding polypeptide including Potl, TRF1, TRF2, PinX1, Rapl, Tin2, Tankyrase, TANK2 and Ku70/80, where the polypeptide having telomerase catalytic activity comprises any catalytic subunit of any mammalian telomerase reverse transcriptase. The encoded chimeric molecule is from any from any biological source having any amino acid sequences for which no structure is apparent, and encompasses all mutants and variants thereof.

The specification provides guidance, prediction, and working examples for an isolated polynucleotide comprising SEQ ID NO: 1, a vector comprising said isolated polynucleotide comprising SEQ ID NO: 1, composition comprising said isolated polynucleotide comprising SEQ ID NO: 1, and an isolated cell comprising said isolated polynucleotide comprising SEQ ID NO: 1. However, the specification does not provide guidance, prediction, and working examples for making and using the nucleic acid as claimed.

Thus, an undue amount of trial and error experimentation must be preformed where such experimentation involves searching and screening a vast number of biological sources for the claimed nucleic acid and determining whether the nucleic acid encodes a functional chimeric molecule that have both telomerase catalytic activity and telomere binding activity. Alternatively, trial and error experimentation involves making amino acid substitutions, deletions, additions, and combinations thereof to the polypeptide encoded by SEQ ID NO: 1 to make the encompassed mutants and variants thereof, and searching and screening for encoded chimeric molecules that have both telomerase catalytic activity and telomere binding activity. General teaching regarding screening and searching for the claimed invention is not guidance for making the claimed invention.

Therefore, in view of the overly broad scope of the claims, the specification's lack of specific guidance and prediction, the specification's lack of additional working examples, and the amount of experimentation required; it would require undue experimentation for a skilled artisan to make and use the claimed invention. Without sufficient guidance, the experimentation left to those skilled in the art is unnecessarily and improperly extensive and undue. See *In re Wands* (858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988).

Conclusion

7. Claim 10 is allowed.

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L Fronda whose telephone number is (571)272-0929. The examiner can normally be reached Monday-Thursday and alternate Fridays between 9:00AM - 5:00PM. If attempts to reach the examiner by telephone are unsuccessful, the

examiner's supervisor, Andrew Wang can be reached on (571)272-0811. The fax phone number for the organization where this application or proceeding is assigned is (571)273-8300.

10. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Christian L. Fronda/
Primary Examiner
Art Unit 1652